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04/11/2012 08:44 AM

To "Patricia L Cowall-Hanover"
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cc

bcc

Subject JUST FYI

Hi Pat, Here are my notes just FYI. These are completely draft so please don't post yet.
KR, Jess

From: Skorupski, Jessica Dunn [JRDUS]
Sent: Thursday, March 29, 2012 4:08 PM
To: jessica.skorupski@yahoo.com
Subject: RE: Agenda Topics for SPL ER/DL TC at 1:00pm ET

AGENDA

- Update on D&B Collaboration – Jessica Skorupski

Will there be a central mailbox to send inquiries? D&B stated there are always issues requiring manual override (foreign addresses). Ryan indicated they may approach FDA to discuss relaxing the confidence level. Currently it's level 10. What are the different confidence levels (Jess f/u)?

- Issues arising when the establishment names in NDAs are different from the name in DER submissions (and DUNS information) – Jackie Mohns

BMS working internally to create a global dossier of all filing documents. Mfg from investigational for NDA submission. For US, D&B, FDA Guidelines, CMC colleagues providing different site information for the different sites foreign addresses. Word order, commas, punctuation. US registrations alignment between dossier and ERs. Reign in the CMC folks who do registrations and fore them to use the FDA registered information rather than that coming from other sources (ie, affiliates). ERs should match documentation in NDAs. Complication exists mostly with 3rd party manufacturers. EU may recognize a company address differently than US.

- Scenario - Beverly Haslip: We recently received a SPL validation error from **CBER** for a **One-count carton finished pack** where originally the carton and inner syringe NDC were the same. CBER requested/required that a different NDC be used for each level of packaging. Historically for this type of packaging configuration, for both CBER and CDER products, our company has used the same NDC for both the carton and the inner product,. Lonnie has previously indicated that for **CDER** products, the elist system expects different NDC's for a pack where there is multilevel packing (different types of packaging); however, at this time CDER has not implemented this validation rule. We wanted to get the groups' perspective about the application of this rule to CDER products, and see if anybody was implementing or is in the process of evaluating the use of two different NDC pack codes:.
 - for a One-count finished pack e.g., one vial contained within a carton
 - Multi-count carton e.g., 10 vials contained within a carton

CBER requirement, not CDER requirement.

Multi level pkg with 2 different NDCs to represent the 2 levels of pkg. Single count finished pack biologic product where NDC on inside item was the same as what was on the carton. CBER said the internal product needed a different NDC than the outer carton. Some companies making such products are currently evaluating CDER products to do an inventory to see which are in cartons. What is the group's perspective on this? CDER said they're not implementing a validation rule requiring a different NDC for each different level of pkg. but this could be implemented. immediate

Paul Loebach said they do not think this would be coming from CDER drugs, but.... Veda Perkins is going to give consideration to this per request. Merck, GSK has had issues. Bloodstuff, vaccines and 1 other category. Validation rule came up in January. In a pouch to protect the product, don't want the syringe to have a different NDC code since that might lead to someone thinking it didn't need to be pouched. We believe FDA has been discussing this for some time. Hospira addresses different package levels in the barcode.

We can follow-up with the minutes from Paul, Paul Loebach.

Current process on new vaccines is to assign it at different levels for CBER products only. For CMS, there could be reimbursement preferences for multiple vials in a saleable bulk package (ie 10).

Perrigo is also having NDC issues. NDC assignment is getting much higher profile within companies and new considerations. Across industry.

Nor currently evaluating single bottle in 1 carton to have different NDCs. If multiple bottles, then there is a different product code.

- AOB

Teleconference information:

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